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Description

Field of the Invention

[0001] The invention relates to devices for placing and securing a vascular graft in a predetermined location in a patient's vascular system.

Background of the Invention

[0002] It has been long accepted practice to treat a variety of vascular disorders in a surgical procedure that involves placement of a vascular graft in a patient's vascular system. The construction and characteristic of the graft typically will be adapted to optimize its use in the specific surgical environment and condition to be treated and, accordingly, a number of different types of grafts are available. Among the most common types of vascular grafts are those formed from a woven or knitted tubular fabric as well as non-fabric tubes such as expanded polytetrafluoroethylene. Such grafts typically are placed in a patient's vascular system in a highly invasive surgical procedure. In general, the complexity of the surgical procedure required to place the graft will depend on many factors, including the location and surgical accessibility of the portion of the patient's vasculature where the graft is to be placed.

[0003] Not all vascular conditions in which it would be desirable to place a graft can be so treated. Among the particularly troublesome medical conditions in which it is desirable to place a graft is that of an abdominal aortic aneurysm, in which a portion of the patient's aorta, the major artery carrying blood from the heart, has developed a weakened wall such that the weakened portion will tend to expand under the influence of the patient's blood pressure. An aortic aneurysm presents a life threatening risk that the aneurysm may burst causing massive internal bleeding. Treatment of the condition typically has involved deeply invasive abdominal surgery in which the patient's abdominal cavity is opened to reach and expose the aortic aneurysm. While maintaining the patient on an independent life support system, the region of the aneurysm is incised lengthwise to enable insertion of the graft into the aorta to span the weakened region and define a structurally round flow path between the remaining healthy portions of the aorta. The graft so positioned then is sutured in place. The graft thus serves as a reinforcing liner for the weakened portion of the aorta. Such surgical procedures have been characterized by a relatively high mortality rate. Typically, patients suffering from the condition are elderly and are less able to survive the rigors of major abdominal surgery. Additionally, there is a substantial degree of risk when the abdominal cavity is opened because the confining pressure of other abdominal organs on the aorta is released. In some cases, the abdominal wall in the region of the aneurysm is so weak that upon release of the confining pressure, the aneurysm bursts with resulting immediate massive hemorrhaging.

[0004] It would be desirabl , therefore, to provide an apparatus and system for placement of a graft, such as, but not limited to, placement in the abdominal aortic region, with a less invasive procedure that presents less risk to the patient. It is among the general objects of the invention to provide such a system.

Brief Description of the Prior Art

[0005] Mirich et al., in "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study", Radiology (March 1989), describes the use of NYLON™ covered, self-expanding metallic stents to repair abdominal aortic aneurysms that were artificially produced in dogs. Mirich et al. describes a graft framework constructed from three self-expanding metallic zigzag stents connected in tandem. The two lower stents are covered with NYLON. The graft is anchored in position by barbs attached to both ends of the graft. Delivery of the framework is achieved by compressing the NYLON covered graft and advancing it through a catheter with a blunt tipped introducer wire. When the NYLON covered portion of the graft bridges the aneurysm, the introducer wire is held in place and the catheter slowly withdrawn. This releases the graft assembly and allows the stents to expand until they against the vessel walls.

[0006] In a similar procedure, Lawrence Jr. et al., in "Percutaneous Endovascular Graft: Experimental Evaluation", Radiology (May 1987), discloses the use of an expanding stent of the type disclosed in U.S, Patent No. 4,580,568 (Gianturco) to anchor and support a DACRON™ graft. The Gianturco stent comprises a wire formed into a closed zigzag configuration by creating an endless series of straight sections joined by bends. The stent is resiliently collapsible into a smaller generally tubular, low profile shape. In its compressed, low profile shape, the straight sections are arranged side-by-side, in close proximity, to facilitate insertion. The stent is resiliently expandable such that the straight sections press against the wall of the artery to maintain it open when the stent is permitted to resiliently expand.

[0007] The procedure disclosed by Lawrence Jr. et al. includes the use of a plurality of Gianturco stents in tandem. DACRON tubing is wrapped around the outside of the middle group of the stents, internalizing the stents within the graft. As a result, the lead and trail stents act as anchors, while the internal stents served to open the tubular graft when the device is released from the catheter. As with the procedure disclosed by Mirich et al., a catheter is used to deliver the graft framework to the treatment site.

[0008] The use of expanding stents is discussed further by Dobben et al. in "Prosthetic Urethra Dilatation with the Gianturco Self-expanding Metallic Stent: A Feasibility Study in Cadaver Specimens and Dogs", AJR 156:757-761 (April 1991). Dobben et al. describes the

us of stainless steel stents bent into a zigzag pattern and then formed into a cylinder. Stents having flared ends as well as stents that are not flared are discussed. The stents ar said to have been delivered to a predetermined location by using a coaxial TEFLON™ introducer system. The flared stents were said to have been flared outwardly at both ends, and, when fully expanded, had a smaller diameter in the center than at the ends.

[0009] WO-A-8908433 discloses a graft with the technical features of the pre-characterising part of claim 1 below.

Summary of the Invention

[0010] The present invention is defined to claim 1 below. The invention relates to a device and system for the minimally invasive, percutaneous placement of a vascular graft, such as in the repair of an abdominal aortic aneurysm. The device includes a tubular synthetic graft having proximal and distal ends. When placed, the graft is held in position in the blood vessel by one or more resilient self-expanding anchors. In one embodiment, the anchor is formed from a single, continuous wire bent in a zigzag configuration to define a series of elongate wire segments connected by bends. The anchor defines a three-dimensional generally tubular structure having proximal and distal ends. The anchor is compressible to a low profile (small diameter) and can expand resiliently to an enlarged diameter.

[0011] In one embodiment of the invention, curved wire segments of the anchor define somewhat of an hourglass configuration in which the mid-portion of the generally tubular anchor defines a narrowed waist that is smaller in diameter than at the ends. The anchor is attached to an end of the tubular synthetic graft. The diameter of the fully expanded graft preferably may be less than the fully expanded, relaxed diameter of the anchor so that, when an end of the anchor is attached to the graft, the graft will open fully. The end of the anchor that is attached will be contracted somewhat, thereby accentuating the radially outward curvature of the other (distal) end of the anchor. The distal end of the anchor thus is adapted to bear against the wall of the blood vessel at a plurality of points (in the region of the bends) rather than along the full length of the wire segments. By so concentrating the point of contact of the anchor with the blood vessel, a more secure attachment of the anchor to the vessel wall is achieved thereby reducing the risk of the device migrating downstream in the blood vessel.

[0012] In another aspect of the invention, the curved configuration of the wire segments is such that the attached (proximal) end of the anchor can be attached to the distal end of the synthetic graft in a manner that provides for a relatively smooth transition between the two. By minimizing the extent to which portions of the anchor protrude radially inwardly into the graft, the cross-sectional area of th lumen through the graft is not compromised. This is desirable, for example, should it be necessary to subsequently tr at the patient with a catheter that must be passed through th graft. Th absence of radially inwardly protruding anchor portions reduces the risk that the subsequently introduced catheter or other vascularly insertable member might become caught on the anchor.

[0013] Although the anchor may be attached to the graft by sutures, it is preferred to capture a marginal end portion of the graft within a pair of wires that define a portion of the anchor. The wire portions may be welded together in a manner that captures a marginal end portion of the graft without the use of bulky sutures.

[0014] Attachment of the anchor to the vessel wall may further be enhanced by one or more radially outwardly protruding hooks attached to the wire segments. The hooks engage the vessel wall under the influence of the resilient anchor and enhance the anchor's resistance to migration once the graft is properly positioned. The hooks preferably are formed on the end of short segments of wire that are welded to the anchor to locate the hooks at regions adjacent to the distal bends. The hooks extend a short distance beyond the bends and become engaged in the blood vessel wall once the anchor is expanded.

[0015] The graft assembly is delivered percutaneously with a catheter-like delivery device that includes an outer sheath and an inner positioning member that extends through the outer sheath. The graft assembly is compacted to its low profile configuration and is loaded within the distal end of the sheath. The delivery device then is advanced into the patient's vascular system in an over-the-wire technique. The positioning member has a hollow lumen adapted to receive the guidewire. When the delivery system and graft assembly have been advanced to the intended site of deployment, the positioning member is held stationary while the sheath is withdrawn. As the sheath withdraws, the anchor and graft are progressively exposed so that the anchor can expand and resiliently engage the wall of the blood vessel.

[0016] The present invention aims to provide an improved percutaneously deliverable vascular prosthesis that avoids post implantation migration.

[0017] The invention aims to provide an improved system for more securely anchoring and positioning the vascular graft within a blood vessel. The invention provides a percutaneously placeable graft assembly that includes a graft and a resiliently expandable anchor attached to the graft in which the anchor is configured to concentrate the expansion force developed by the anchor at a plurality of discrete locations.

Brief Description of the Drawings

[0018] Th foregoing and other objects and advantages of the invention will be appreciated more fully

from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a side elevation of one embodiment of the graft assembly;
FIG. 2 is an enlarged elevation of the anchor shown in the graft assembly of FIG. 1;
FIGS. 3A and 3B are, respectively, diagrammatic cross-sectional views of a curved anchor in accordance with the present invention contrasted with a straight stent within a vessel;
FIG. 4 is a detailed somewhat diagrammatic illustration of the attachment of the anchor, by sutures, to the graft;
FIG. 5 is an illustration of a curved anchor segment and attached hook;
FIG. 6 is an illustration of a portion of the anchor as seen from the right of FIG. 5;
FIG. 7 is an enlarged illustration of the hook arrangement in FIG. 5;
FIG. 8 is an enlarged illustration of the hook arrangement in FIG. 6;
FIG. 9 is an illustration of the distal end of a graft having holes adapted to receive and be attached to an anchor;
FIGS. 10 and 11 are illustrations of the manner in which an anchor may be attached to the graft as shown in FIG. 9.
FIG. 12 is a diagrammatic illustration of a graft assembly with the distal anchor attached to the distal end of the graft and in a relaxed configuration;
FIG. 13 is an illustration of a graft in accordance with the invention implanted in the aorta so that the graft spans an aortic aneurysm;
FIG. 14 is an illustration of the delivery device for the graft assembly;
FIG. 15 is an enlarged sectional illustration of the distal region of the delivery device loaded with the graft assembly and in readiness for insertion into the patient and
FIG. 16 is a diagrammatic illustration of the manner in which the graft assembly may be loaded into the distal end of the delivery device.

Detailed Description of the Invention

[0019] FIG. 1 illustrates one embodiment of a graft assembly, indicated generally at 10, adapted for use in the present invention. The assembly 10 includes a synthetic vascular graft 20 that is intended to be placed within a patient's blood vessel, the invention being described, for example, in connection with the treatment of an abdominal aneurysm. The graft 20 is tubular and may be formed from materials and in any of a variety of constructions known in the art. For example, the graft may be formed from expanded polytetrafluoroethylene with a porosity and internodal distance similar to grafts presently commercially available. Alternately, the graft may be formed from a fabric material, either woven or knitted, or in other configurations known in the art. Preferably, the graft has a porosity that will exhibit the desired properties of promoting tissue ingrowth while precluding undesired blood leakage. The graft preferably is provided with one or more radiopaque stripes to facilitate fluoroscopic or X-ray observation of the graft. The stripes may be formed in the graft by any conventional means as will be appreciated by those skilled in the art. The assembly 10 also includes an anchor 30 that is secured to the distal end of the graft and serves to retain the graft in position in the blood vessel.

[0020] FIG. 2 shows, somewhat diagrammatically, the anchor 30. The anchor 30 may be made from a single continuous length of metal wire. The wire preferably may be an alloy of nickel (35%), cobalt (35%), chromium (20%), and molybdenum (10%). Such wire is available from Maryland Specialty Wire Company, Cockeysville, Maryland under the trade designation MP35N. The alloy has high corrosion resistance, is non-magnetic and has a strength comparable to stainless steel. The wire is formed to define a series of wire segments 34 and alternating proximal and distal bends 36P, 36D. The segments 34 and bends 36P, 36D are arranged in a zigzag pattern. The wire segments 34 preferably have the same length. In making the anchor a wire, so bent, is attached, as by welding, at its ends 32A, 32B to form a three-dimensional, generally tubular structure. The resulting anchor is resilient and can be compressed to a low profile, small diameter configuration suited for percutaneous delivery into the patient's vascular system.

[0021] In accordance with the invention, the anchor segments 34 are curved so that the anchor defines somewhat of an "hourglass" shape, having proximal and distal ends 35, 37 that define approximately the same diameter (when the anchor 30 is in its relaxed state) and a narrowed diameter waist portion 38.

[0022] Although the embodiment illustrated in FIG. 1 is shown as having a graft with an expanded diameter substantially corresponding to the diameter of the proximal and distal ends 35, 37 of the anchor, it is preferred to configure the anchor 30 and graft 20 so that the distal end of the anchor defines somewhat of a larger diameter. Thus, when the anchor 30 is used within the body, the proximal end 35 of the anchor 30 may expand the distal end of the graft to its open configuration and the distal end 37 of the anchor 30 may tend to extend radially outward as it extends from its proximal end 35 to its distal end 37, thereby assuring that the distal end of the anchor will engage the wall of the blood vessel.

[0023] The security of the engagement between the anchor 30 and the aorta wall may be further enhanced by hooks suggested diagrammatically at 40, which are secured to the anchor 30. The hooks 40, as suggested in FIG. 2, are formed on the distal ends of hook wire segments 42. The hook wire segments 42 preferably are formed from the same material as the main wire of the anchor 30. They are secured along the anchor seg-

ments 34, such that the hooks 40 are disposed beyond the distal bends 36D. The segments 42 are welded to the anchor segment 34 at first (proximal) and second (distal) junctions 46, 48. The hooks 40 preferably are sharp and aid in attaching the anchor 30 to the aorta wall to prevent migration after the device is implanted. It should be understood that although FIG. 1 illustrates a hook associated with each of the anchor segments 34, it may not be necessary to include a hook for each anchor segment.

[0024] The curved configuration of the anchor segments serves several purposes. It results in a decrease in the surface area along which the anchor 30 engages the vessel wall. That, in turn, concentrates the resilient expansion force of the anchor at the point-like regions of contact of the bends 36P, 36D and hooks 40 so that they will tend to more firmly dig into and bear against the vessel wall. The anchor segment 34 may be curved to include an arc of between about 5° to about 30°. The effect of the curved configuration for the anchor segments may be seen from FIGS. 3A and 3B which show, diagrammatically, the contrast between the surface area of the anchor 130 in contact with the vessel wall 102 when a straight segment 138 (such as disclosed in the Gianturco patent) is used and the surface area of the anchor 30 in contact with the vessel wall 102 when a curved anchor segment 34 is used. As shown in FIG. 3B with an anchor having straight segments, the straight segments merely press flat against the vessel wall 102 and, even if provided with hooks, may not securely attach themselves to the vessel wall. Additionally, where, as is often the case, the inner luminal surface of the blood vessel may have irregularities, only portions of the straight segments may press against the high spots of the irregularities. In contrast, in the present invention, illustrated in FIG. 3A, the curved configuration of the wire segments 34 tends to space a major portion of the segments 34 from the wall of the blood vessel so that only the ends of the anchors will tend to engage the vessel wall. Consequently, the resilient force of expansion of the stent is concentrated in the ends of the anchor which enhances the attachment of the anchor in the blood vessel. Additionally, by concentrating the expansive force of the anchor at a plurality of relatively small area points, the device does not require an anchor having a high degree of spring expansile force. Thus, an anchor having a relatively weak spring force, but in which the force is focused on several relatively small areas, may be used. By using an anchor with a reduced level of expansile force, the risk of complications from the application of an excessive force on an already weakened artery wall is reduced.

[0025] The proximal end of the anchor 30 is secured to the distal end 22 of the graft 20. As shown in FIG. 4, the anchor 30 may be secured to the graft by suturing the proximal end of the anchor 30 to the distal end 22 of the graft 20. The suture 50 is passed through the mesh of the graft 20 and around the proximal bends 36P of the anchor 30. Preferably, the suture 50 is passed about the proximal bends 36P four times, with each successive stitch 51, 52, 53, 54 being further removed from the bend.

[0026] Another advantage of the anchor with curved wire segments is that the proximal end 35 of the anchor, when deployed in the patient, tends to merge smoothly with the body of the tubular graft to form a smooth transition and without any portion of the anchor protruding radially inwardly into the graft lumen. This is desirable particularly in those cases where a catheter may be inserted into the patient's vascular system in a subsequent procedure in which the catheter is passed through the graft. The existence of radially inwardly protruding portions of the anchor could present some risk of the catheter becoming caught on such protruding portion, thus risking injury to the patient, dislodgement of the graft as well as possible damage to the catheter. As shown in the embodiment of FIG. 1, it will be appreciated that the proximal ends of the anchor are attached directly to the distal end of the graft so that when deployed in the patient's blood vessel, the anchor will not have an inwardly protruding portion.

[0027] FIGS. 5 and 6 illustrate, in more representative detail the configuration of a segment 34 of an anchor in accordance with the invention. In this configuration, the wire segments 42 that support the hooks extend more fully toward the proximal bend 36P than in the configuration illustrated in FIGS. 1 and 2. By way of dimensional example, in an anchor adapted for use in an abdominal aortic aneurysm repair prosthesis, the length of the wire segments 34 that make up the anchor 30 may be of the order of 25mm (1.00 inches) long. The hook wire segment 42 on which the hook 40 is formed maybe of the order of 22mm (7/8 of an inch) long with the hook 40 being disposed approximately 3mm (1/8 of an inch) above the distal bend 34D associated with that hook. The wire from which the anchor and the hook segment are made may be of the order of 0.36mm (0.014 inches) diameter. The proximal and distal resistance welds by which the hook segment is secured to the anchor segment may be disposed, respectively 8.5mm (1/3 of an inch) from the proximal bend 36P and about 6mm (1/4 of an inch) from the distal bend 36D. FIG. 5 illustrates a representative degree of curvature for the wire segment and an associated hook segment. By way of example, the degree of curvature may be of the order of 75mm (3 inches) in radius. The relaxed expanded diameter of the anchor 30 may be between about 6 mm to 20 mm, depending on the blood vessel into which it is to be placed.

[0028] FIGS. 7 and 8 illustrate in enlarged detail the configuration of a typical hook 40 and its associate distal bend 36D. The hook is provided with a sharpened tip 50 formed at the end of a generally radially outwardly protruding portion 52. The protruding portion which may be of the order of 1.27mm (0.050 inches) long and may be formed by bending the hook wire 42 from which the

hook is formed about a pin of the order of 1.27mm (.050 inches) in diameter. The bends 36P, 36D may be formed by bending the wire about a pin of the order 9.5mm (3/8 inch) diameter.

[0029] FIGS. 9, 10 and 11 illustrate portions of an assembly incorporating the anchor configuration of FIGS. 5-8 and an improved arrangement for attaching the graft 20 to the anchor 30. As shown in FIG. 9, the distal end of the graft 20 is formed to include a plurality of circumferentially spaced holes 54 disposed slightly proximally of the distal edge 56 of the graft. All edges of the graft including the distal edge 56 as well as the edges defined by the holes may be heat sealed or otherwise treated, if necessary, to prevent unraveling of the graft. By way of example, for an anchor 30 dimensioned as described above, the holes 54 may be of the order of 0.4mm (0.016 inches) diameter and may be spaced approximately 2 mm from the distal edge 56 of the graft. FIGS. 10 and 11 illustrate the manner in which the anchor is attached to the graft. After the anchor 30 is formed as described above, the hook segment 42 is attached by resistance welding but only at one of the junctures 46, 48, preferably, the distal juncture 48. When the desired number of hook segments 42 have been attached to the anchor segments 34, the proximal end 35 of the anchor is inserted into the distal end of the graft 20 but with the proximal, unattached portion of the hook wire segment 42 overlying the outside of the distal margin of the graft and with its proximal end 58 passing inwardly through the hole 54 to the interior of the graft. With the graft and anchor so assembled, the proximal resistance weld 46 may be made. Thus, the marginal portion of the graft is captured between the generally parallel anchor segments 34 and associated hook segments 42 between the proximal and distal junctures 46, 48. This arrangement is preferred to a sutured connection between the anchor and graft in that it cannot become unraveled and, additionally, is less bulky than the sutured connection.

[0030] In a preferred use of the device or system according to the invention, the graft is selected so that when fully expanded, it will match or be slightly larger in diameter than the vessel to which it is to be implanted. It is intended that when the graft is deployed and expanded, the end of the graft will lie as close to the surface of the lumen of the blood vessel as possible in order to enhance tissue ingrowth into the graft wall and provide a smooth transition in the surface that defines the flow area from the healthy portion of the blood vessel into the graft. To that end, the anchor should be selected with respect to the graft so that the relaxed, freely expanded anchor will define a diameter slightly greater than the fully expanded diameter of the graft. That assures that when the device is deployed, the anchor will open the end of the graft fully.

[0031] FIG. 12 illustrates, diagrammatically, the configuration of the assembly when the graft 20 is attached to an anchor 30 as illustrated in FIGS. 9-11. When the graft 20 and attached anchor 30 are permitted to relax, the anchor assumes a distally flared configuration in which the bends 36D and hooks 40 at the distal end define a larger diameter than the inner end of the anchor that is disposed within the graft. In this configuration, the anchor biases th distal end of th graft in its open configuration. It should be understood, however, that when the device is actually deployed in the blood vessel, the segments of the anchor become aligned in generally parallel configuration and in which the proximal bends 36P of the anchor spread apart and lie closely against the inner surface of the graft as suggested in FIG. 13.

[0032] FIGS. 14-16 illustrate the catheter-like device by which the graft assembly may be percutaneously inserted and deployed within the patient's blood vessel. The delivery device includes an elongate flexible sheath 60 formed from a suitable polymeric material and having a fitting 62, including a Tuohy-Borst adapter 64 at its proximal end. The sheath 60 is adapted to receive a positioning tube 66 that has, at its distal tip, a flexible distally tapered dilator 68 and a stop member located proximally of the dilator tip. The proximal end 72 of the dilator tip is dimensioned to be received within the lumen 68 at the distal end of the flexible sheath. The tube 66 is longer than the sheath 60 so that when assembled, the proximal end of the tube 66 will protrude proximally of the Tuohy-Borst sheath adaptor 64. The positioning tube 66 is adapted to receive a guidewire to facilitate placement of the device.

[0033] When the delivery device and graft assembly are arranged in readiness for insertion into the patient, the graft assembly will be contained within the distal end of the sheath and about a portion of the positioning tube as illustrated in enlarged detail in FIG. 15. As suggested diagrammatically in FIG. 16, the graft assembly is loaded into the delivery device using a funnel-like loader 70 having an enlarged distal inlet end 72 and a narrowed proximal outlet end 74 (FIG. 16). The graft assembly is prepared for loading by attaching a long loop 76 of suture material to the proximal end of the graft. FIG. 16, which is diagrammatic and not to scale, illustrates the configuration of the delivery device when loading the graft assembly. The positioning tube 66 will have been extended through the sheath with its distal end extending beyond the distal tip of the sheath so that a step member 78 is spaced from the distal end of the sheath 60 by a distance greater than the length of the graft assembly 20, 30. The funnel 70 is disposed about the positioning tube 66 with the proximal end of the funnel being in communication with the distal outlet end of the sheath. The loop of suture 76 is passed through the funnel and along the lumen 80 of the sheath, exiting at the proximal fitting. The graft assembly is placed over the distal end of the positioning tube 66 in a position such that the proximal bends 36P of the distal anchor 30 are disposed distally of the pusher. The graft assembly then is positioned on the tube 66 to locat the proximal

bends adjacent the stop 78. With the elements so arranged, the positioning tube 66 and suture 76 are drawn together proximally to draw them through the funnel 70. As the positioning tube and graft assembly are drawn through the funnel 70, th graft is progressively constricted to a low profile about the positioning tube. By drawing them in unison, there is no relative lengthwise movement of the graft assembly with respect to the positioning tube. Consequently, as the graft assembly constricts about the positioning tube 66 and is drawn into the distal end of the sheath, the anchor is compressed to a low profile with its proximal bends 36P bearing against the distal face of the stop 78. The tube 66 preferably is provided with a marker 82 (FIG. 14) near its proximal end, the marker being located so that when it is exposed proximally of the fitting 62, the graft assembly will have been withdrawn fully into the distal end of the sheath and the proximal end of the dilator tip also is drawn slightly into the distal tip of the sheath, as shown in FIG. 15. The distal tip of the sheath preferably is provided with an inner lining segment 84 formed from a relatively hard material. The lining segment is dimensioned and located to be aligned with the hooks on the distal end of the distal anchor and serves to prevent the hooks 40 from digging into the softer material from which the sheath is formed. Additionally, the distal liner preferably is formed from a material sufficiently dense to be observed under fluoroscopy. When the device is thus loaded, the proximally extending suture 76 may be cut and pulled out of the device. The device then is in readiness for insertion into the patient and deployment of the graft assembly.

[0034] In the preferred embodiment, the graft assembly is provided with an additional anchor suggested diagrammatically at 31 in FIG. 16. The proximal anchor 31 is desirable in order to stabilize the proximal end of the graft and maintain it in a fully opened position as well as to maintain the graft in contact with the blood vessel wall to provide tissue ingrowth. No hooks are required in connection with the proximal anchor 31.

[0035] The device is inserted percutaneously into the patient's vasculature with the aid of a guidewire. The guidewire 88 may be preliminarily loaded into the lumen of the positioning tube before the delivery device is inserted into the patient or, alternately, the guidewire may be placed separately in a preliminary procedure into the patient's blood vessel. In either case, the delivery device is advanced into the patient's blood vessel, for example, as through the femoral artery when placing a graft assembly to treat an abdominal aneurysm. The guidewire may be advanced independently toward and through the region to be treated. The delivery assembly then may be advanced over the guidewire until the graft assembly is in its intended position. In the case of an abdominal aortic aneurysm, the device would be located so that the distal anchor is located distally of the region of the aneurysm such that the graft, when deployed, can pass through the aneurysm thereby lining the artery. With the delivery device so placed, the position of the positioning tube is maintained while the sheath is withdrawn in a proximal direction. The stationary stop maintains engagement with the proximal ends of the distal anchor thereby preventing proximal movement of the graft assembly while the sheath is withdrawn. As the sheath is progressively withdrawn and the anchor emerges from the distal end of the sheath, the anchor expands into engagement with the inner luminal surface of the blood vessel while simultaneously expanding the distal end of the graft. FIG. 13 illustrates the configuration of the expanded, deployed anchor region from which it may be seen that the proximal ends of the anchor 30 lie firmly against the graft material and, optimally, press the graft at a plurality of discrete regions against the wall of the blood vessel. The hooks at the distal end of the distal anchor embed themselves in the wall of the blood vessel under the influence of the inherent resilience of the anchor. As the sheath is progressively withdrawn, the proximal anchor, if used, also emerges from the sheath and expands into engagement with the blood vessel.

Claims

1. A repair assembly (10) for inhibiting migration of the assembly once it is positioned within a blood vessel, comprising:

   a graft (20) having a proximal end and a distal end;
   a self expanding anchor (30) defining a three dimensional generally tubular shape and secured to said distal end of said graft;
   the assembly being characterised in that:
   said anchor (30) includes curved anchor segments (34) that extend from a proximal end of said anchor to a distal end of said anchor and are oriented such that the diameter of said anchor varies along the longitudinal axis of the anchor, thereby to define a configuration in which the mid-portion of the generally tubular anchor constitutes a waist portion which is smaller in diameter than the distal and proximal ends thereof.

2. A repair assembly according to claim 1, wherein said anchor (30) comprises a single, continuous segment of wire.

3. A repair assembly according to claim 2, wherein said wire includes a series of bends.

4. A repair assembly according to claim 3, wherein said wire has first and second ends that are joined together.

5. A repair assembly according to claims 2, 3 or 4,

wherein said wire is metal.

6. A repair assembly according to any on of the preceding claims wherein at least one hook (40) is secured adjacent said distal end of said anchor (30).

7. A repair assembly according to any one of the preceding claims, wherein said distal end of said graft (20) is secured to said anchor (30) adjacent said proximal end of said anchor.

8. A repair assembly according to any one of the preceding claims, in which the anchor waist portion defines an hourglass shape.

9. An abdominal aortic aneurysm repair device comprising:

a cylindrical graft (20) that is adapted to be positioned within a blood vessel to encourage tissue ingrowth, wherein said graft (20) includes a proximal end and a distal end;
a self-expanding anchor (30) defining a three dimensional generally tubular shape and secured to said distal end of said graft (20) to inhibit migration of said graft once it is properly positioned within a blood vessel;
wherein said anchor (30) further includes a proximal end and a distal end, and said distal end of said graft is secured to said anchor adjacent said proximal end of said anchor;
wherein said anchor (30) includes a single, continuous segment of metal wire having a series of zigzag bends, said wire including a first end and a second end, wherein said first and second ends are joined together to form a three-dimensional structure having a generally tubular shape with a longitudinal axis, said anchor (30) also including at least one hook (40) secured adjacent said distal end of said anchor;
characterised in that:
said anchor further includes curved wire segments (34) formed between said bends, wherein said wire segments are oriented such that the diameter of said anchor varies along said longitudinal axis thereby to define a configuration in which the mid-portion of the generally tubular anchor constitutes a waist portion which is smaller in diameter than the distal end portions thereof.

Patentansprüche

1. Reparaturaufbau (10) zum Verhindern der Migration des Aufbaus, wenn er einmal innerhalb eines Blutgefäßes positioniert ist, umfassend:

ein Transplantat (20) mit einem proximalen Ende und einem distalen Ende;

einen selbstaufweitenden Anker (30), der eine dreidimensionale, im allgemeinen röhrenförmige Form definiert und an dem distalen Ende des Transplantats befestigt ist;
wobei der Aufbau dadurch gekennzeichnet ist, daß

der Anker (30) gekrümmte Ankersegmente (34) aufweist, die sich von einem proximalen Ende des Ankers zu einem distalen Ende des Ankers erstrecken und so orientiert sind, daß sich der Durchmesser des Ankers entlang der Längsachse des Ankers ändert und dabei eine Gestalt definiert, bei der der Mittelbereich des im allgemeinen röhrenförmigen Ankers einen Taillenbereich darstellt, der einen geringeren Durchmesser besitzt als die distalen und proximalen Enden derselben.

2. Reparaturaufbau gemäß Anspruch 1, wobei der Anker (30) ein einzelnes, kontinuierliches Drahtstück umfaßt.

3. Reparaturaufbau gemäß Anspruch 2, wobei der Draht eine Reihe von Biegungen aufweist.

4. Reparaturaufbau gemäß Anspruch 3, wobei der Draht erste und zweite Enden besitzt, die zusammen verbunden sind.

5. Reparaturaufbau gemäß Anspruch 2, 3 oder 4, wobei der Draht aus Metall ist.

6. Reparaturaufbau gemäß einem der vorhergehenden Ansprüche, wobei zumindest ein Haken (40) neben dem distalen Ende des Ankers (30) befestigt ist.

7. Reparaturaufbau gemäß einem der vorhergehenden Ansprüche, wobei das distale Ende des Transplantats (20) an dem Anker (30) neben dem proximalen Ende des Ankers befestigt ist.

8. Reparaturaufbau gemäß einem der vorhergehenden Ansprüche, wobei der Taillenbereich des Ankers die Form einer Sanduhr definiert.

9. Reparatureinrichtung für eine abdominale Aortaerweiterung, umfassend:

ein Zylinderförmiges Transplantat (20), das zum Positionieren innerhalb eines Blutgefäßes geeignet ist, um das Hineinwachsen von Gewebe zu verstärken, wobei das Transplantat (20) ein proximales Ende und ein distales Ende

aufweist;

einen sich selbst aufweitenden Anker (30), der eine dreidimensionale, im allgemeinen röhrenförmige Form definiert und an dem distalen Ende des Transplantats (20) befestigt ist, um eine Migration des Transplantats zu verhindern, wenn er einmal ordnungsgemäß innerhalb eines Blutgefäßes eingesetzt ist;

wobei der Anker (30) weiterhin ein proximales Ende und ein distales Ende aufweist und das distale Ende des Transplantats an dem Anker neben dem proximalen Ende des Ankers befestigt ist;

wobei der Anker (30) einen einzelnen, kontinuierlichen Abschnitt aus Metalldraht mit einer Reihe von Zickzackbiegungen aufweist, wobei der Draht ein erstes und ein zweites Ende aufweist, wobei die ersten und zweiten Enden zusammen verbunden sind, um einen dreidimensionalen Aufbau mit einer im allgemeinen röhrenförmigen Form mit einer Längsachse zu bilden und der Anker (30) auch zumindest einen Haken (40) aufweist, der neben dem distalen Ende des Ankers befestigt ist;
dadurch gekennzeichnet, daß

der Anker weiterhin gekrümmte Drahtabschnitte (34) aufweist, die zwischen den Biegungen gebildet sind, wobei die Drahtsegmente so orientiert sind, daß sich der Durchmesser des Ankers entlang der Längsachse ändert und dabei eine Gestaltung definiert, bei der der Mittelbereich des im allgemeinen röhrenförmigen Ankers einen Taillenbereich darstellt, der bezüglich des Durchmessers kleiner ist als die distalen Endbereiche desselben.

Revendications

1. Ensemble de réparation (10) pour empêcher toute migration de l'ensemble une fois qu'il a été mis en place à l'intérieur d'un vaisseau sanguin, comprenant :

   une prothèse endovasculaire (20) ayant une extrémité proximale et une extrémité distale;
   un dispositif d'ancrage auto-dilatable (30) définissant une forme en trois dimensions généralement tubulaire et fixée à ladite extrémité distale de ladite prothèse endovasculaire;
   l'ensemble étant caractérisé en ce que :
   ledit dispositif d'ancrage (30) comprend des segments de dispositif d'ancrage incurvés (34) qui se dilatent depuis une extrémité proximale dudit dispositif d'ancrage vers une extrémité distale dudit dispositif d'ancrage et sont orientés d tell sorte que le diamètr dudit dispositif d'ancrage varie l long de l'axe longitudinal du dispositif d'ancrage, définissant ainsi une configuration selon laquelle la partie médiane du dispositif généralement tubulaire constitue une partie rétrécie qui présente un diamètre plus petit que ses extrémités distale et proximale.

2. Ensemble de réparation selon la revendication 1, dans lequel ledit dispositif d'ancrage (30) comprend un seul segment de fil continu.

3. Ensemble de réparation selon la revendication 2, dans lequel ledit fil comprend une série de courbures.

4. Ensemble de réparation selon la revendication 3, dans lequel ledit fil possède des première et seconde extrémités qui sont réunies.

5. Ensemble de réparation selon les revendications 2, 3 ou 4, dans lequel ledit fil est métallique.

6. Ensemble de réparation selon l'une quelconque des revendications précédentes, dans lequel au moins un crochet (40) est fixé de manière adjacente à ladite extrémité distale dudit dispositif d'ancrage (30).

7. Ensemble de réparation selon l'une quelconque des revendications précédentes, dans lequel ladite extrémité distale de ladite prothèse endovasculaire (20) est fixée audit dispositif d'ancrage (30) de manière adjacente à ladite extrémité proximale dudit dispositif d'ancrage.

8. Ensemble de réparation selon l'une quelconque des revendications précédentes, dans lequel la partie rétrécie du dispositif d'ancrage définit une forme de sablier.

9. Dispositif de réparation aortique abdominale comprenant :

   une prothèse endovasculaire cylindrique (20) qui est adaptée pour être mise en place à l'intérieur d'un vaisseau sanguin pour favoriser la croissance tissulaire, dans lequel ladite prothèse endovasculaire (20) comprend une extrémité proximale et une extrémité distale;
   un dispositif d'ancrage auto-dilatable (30) définissant une forme en trois dimensions généralement tubulaire et fixé à ladite extrémité distale de ladite prothèse endovasculaire (20) pour empêcher toute migration de ladite pro-

thèse endovasculaire une fois qu'elle est mise en place correctement à l'intérieur d'un vaisseau sanguin ;

dans lequel ledit dispositif d'ancrage (30) comprend en outre une extrémité proximale et une extrémité distale, et ladite extrémité distale de ladite prothèse endovasculaire est fixée audit dispositif d'ancrage adjacent à ladite extrémité proximale dudit dispositif d'ancrage ;

dans lequel ledit dispositif d'ancrage (30) comprend un segment unique continu de fil métallique comprenant une série de courbures en zigzag, ledit fil comprenant une première extrémité et une seconde extrémité, dans lequel lesdites première et seconde extrémités sont réunies pour former une structure en trois dimensions ayant une forme généralement tubulaire avec un axe longitudinal, ledit dispositif d'ancrage (30) comprenant également au moins un crochet (40) fixé de manière adjacente à ladite extrémité distale dudit dispositif d'ancrage ;

caractérisé en ce que :

ledit dispositif d'ancrage comprend en outre des segments de fil incurvés (34) formés entre lesdites courbures, dans lequel lesdits segments de fil sont orientés de telle sorte que le diamètre dudit dispositif d'ancrage varie le long dudit axe longitudinal, définissant ainsi une configuration selon laquelle la partie médiane du dispositif d'ancrage généralement tubulaire constitue une partie rétrécie qui présente un diamètre inférieur à ses parties d'extrémité distale.

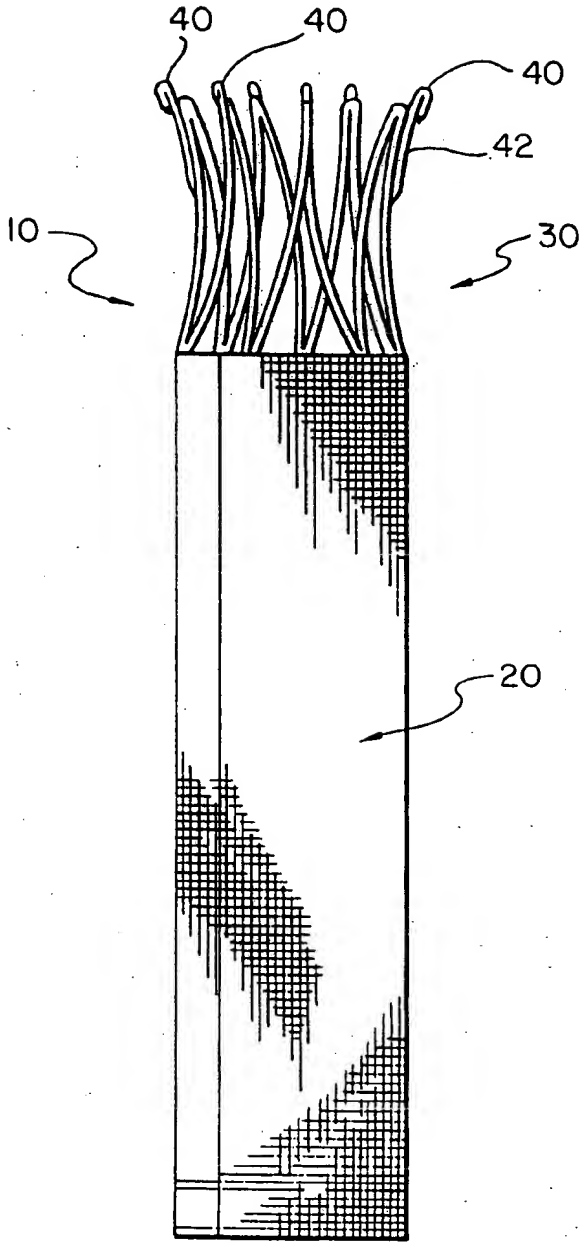

Fig.1

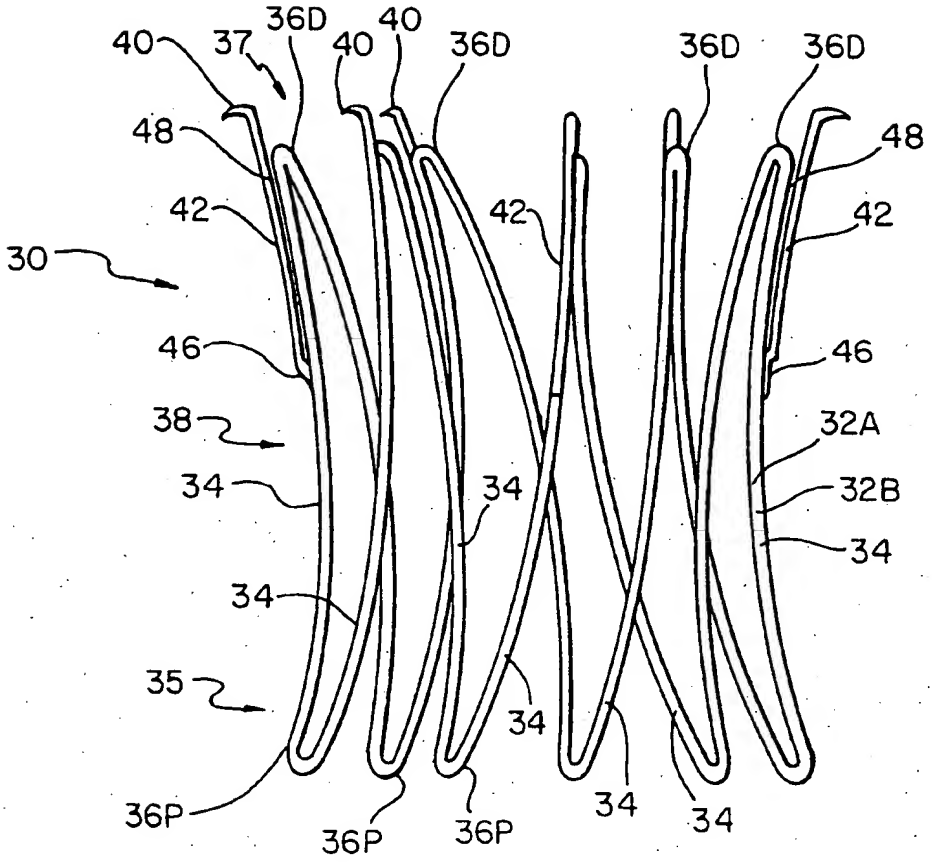

Fig. 2

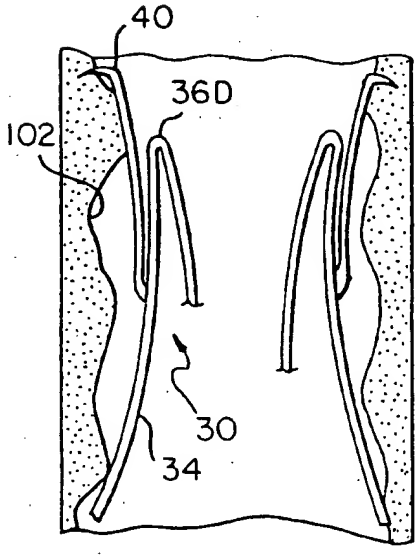

Fig.3A

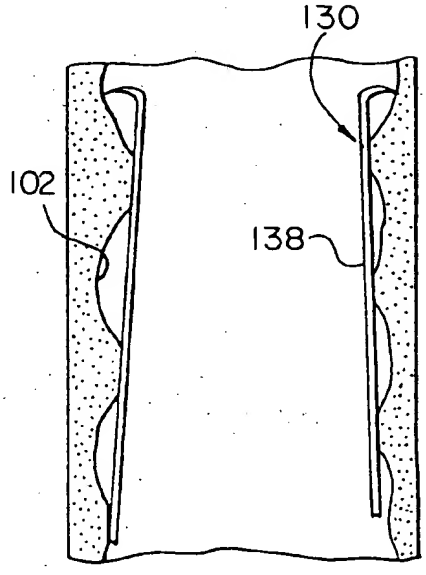

Fig.3B

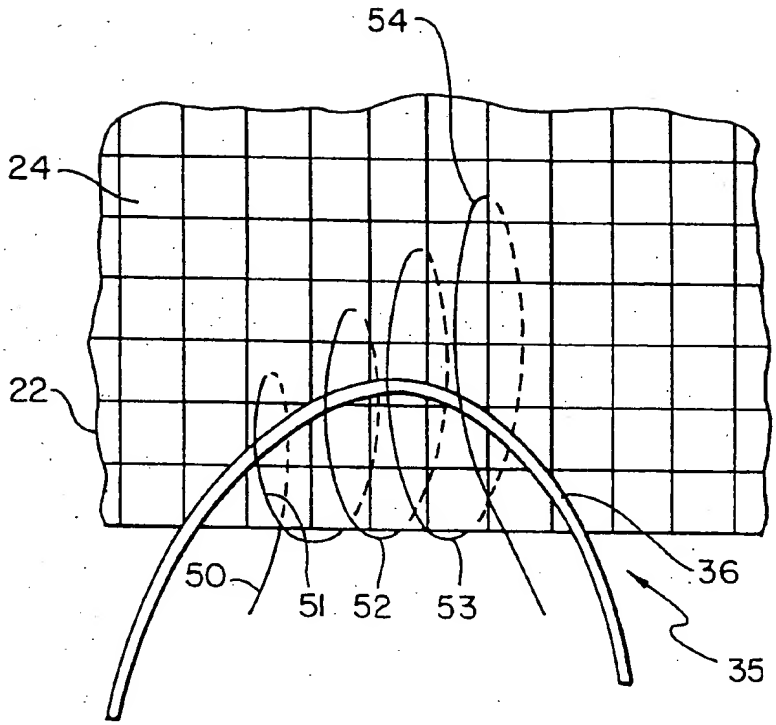

Fig. 4

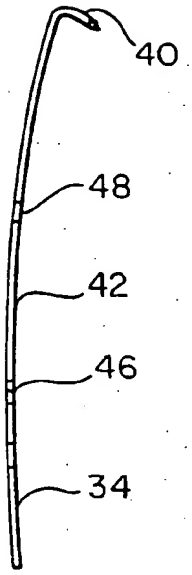

Fig.5

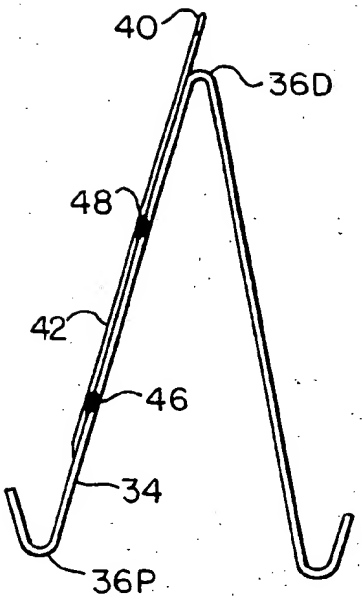

Fig.6

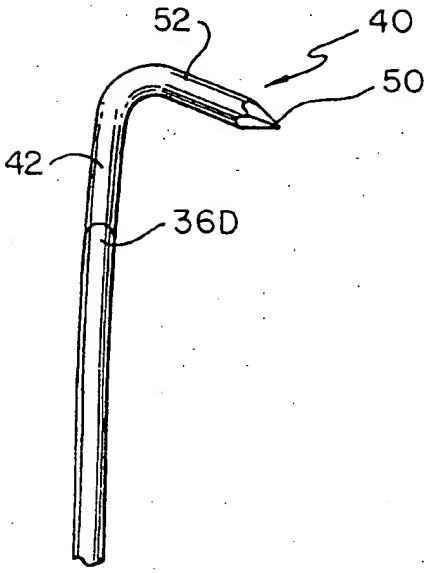

Fig.7

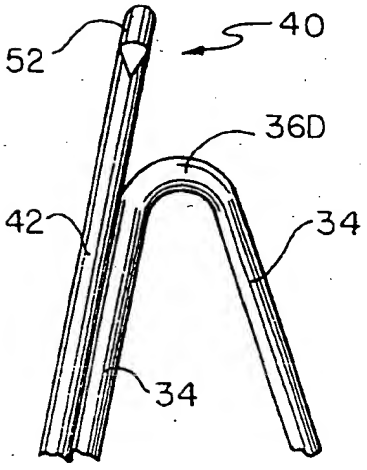

Fig.8

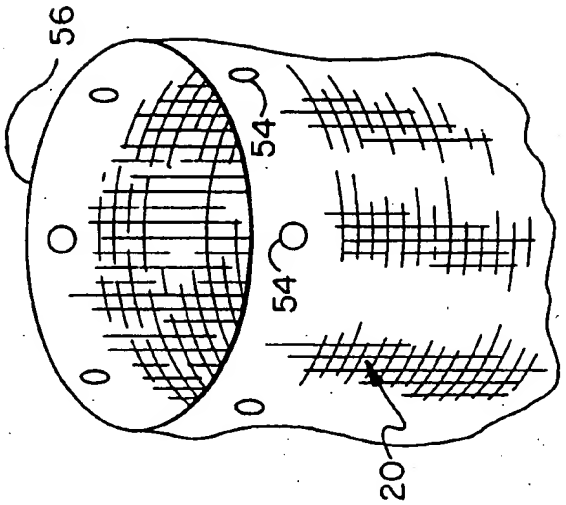

Fig.9

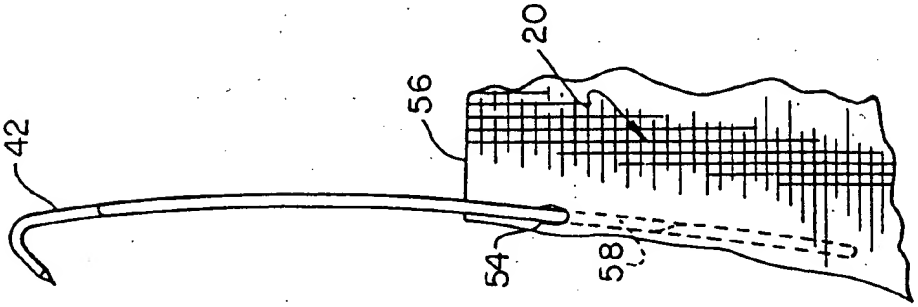

Fig.11

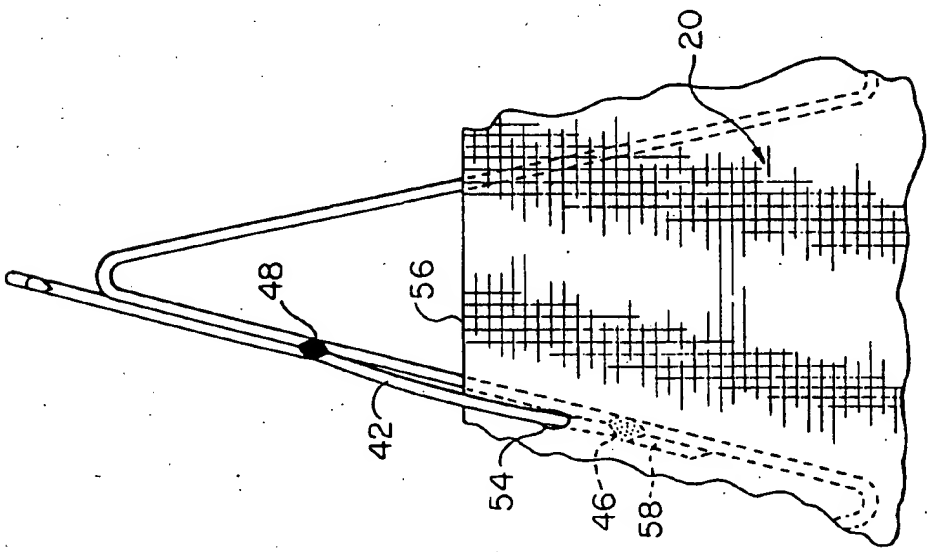

Fig.10

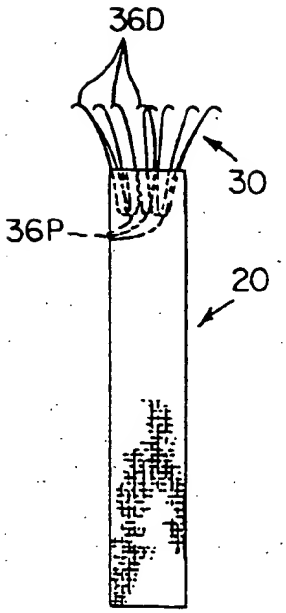

Fig. 12

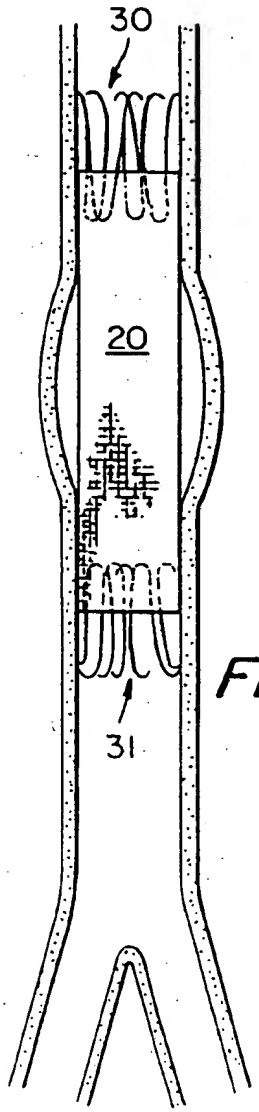

Fig. 13

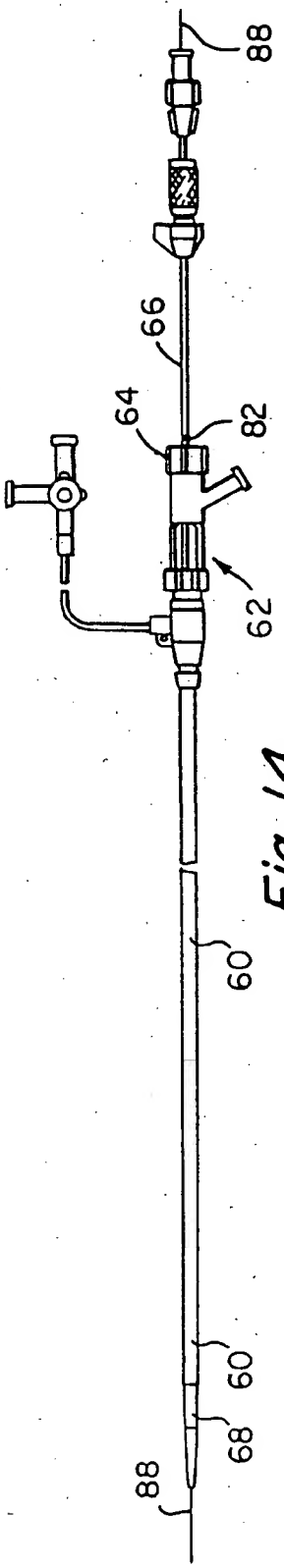

Fig. 14

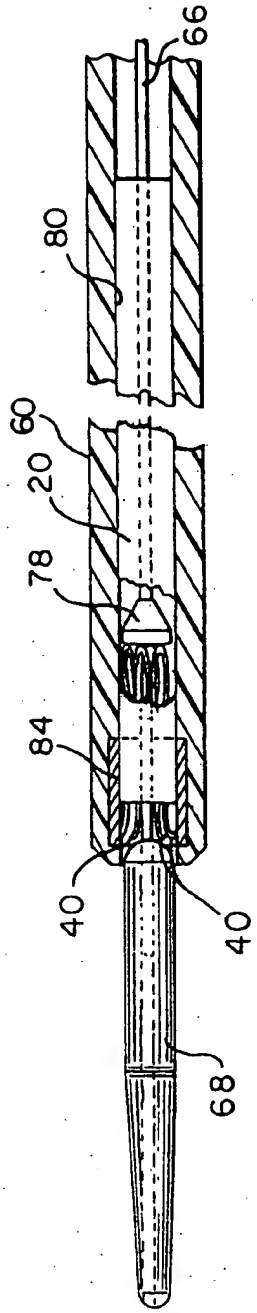

Fig. 15

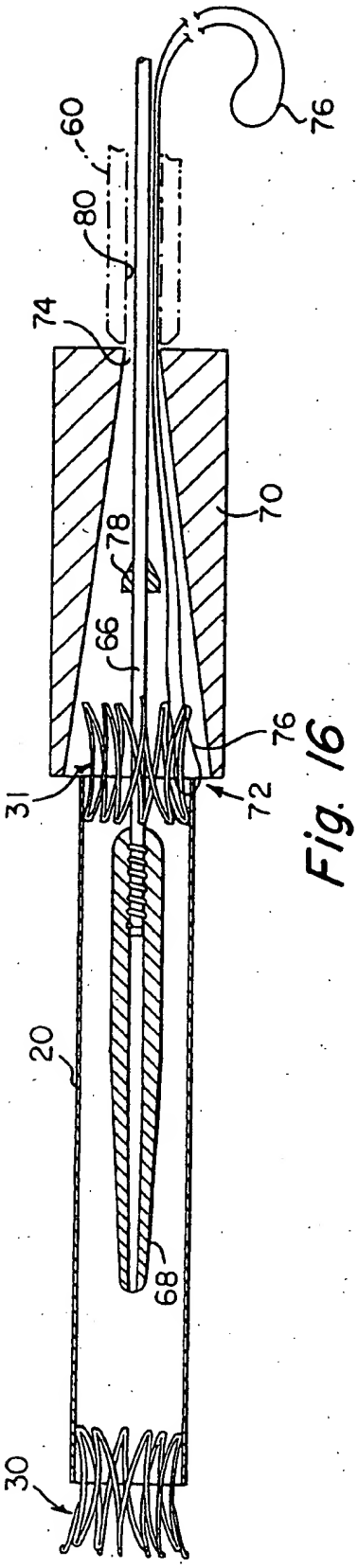

Fig. 16